IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION,	)	
Plaintiffs,	)	C. A. No. 98-80 (SLR) (Consolidated with C. A. No. 98-314 (SLR) and C. A. No. 98-316 (SLR))
v.	)	
MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC.,	)	
Defendants.	)	

MEDTRONIC'S OPENING POST-TRIAL BRIEF ON ACS'S INEQUITABLE CONDUCT BEFORE THE U.S. PATENT AND TRADEMARK OFFICE

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TABLE OF CONTENTS

NATURE AND STAGE OF PROCEEDINGS 1

SUMMARY OF ARGUMENT 1

PROPOSED FINDINGS OF FACT 4

A. Certain Relevant Prior Art 4

B. ACS's Knowledge Of The Boneau Prior Art 7

C. The Lau Patents 14

D. ACS's Unexplained Failure To Disclose The Boneau Prior Art 17

ARGUMENT 21

I. GENERAL INEQUITABLE CONDUCT STANDARDS 21

II. THE ACS REPRESENTATIVES HAD KNOWLEDGE OF THE BONEAU PRIOR ART BUT DID NOT TIMELY OR FULLY DISCLOSE IT TO THE PTO 22

III. THE BONEAU PRIOR ART WAS MATERIAL, AND ACS'S REPRESENTATIVES KNEW, OR SHOULD HAVE KNOWN, IT WAS MATERIAL 25

A. The Boneau Prior Art Was Material To The '154 Patent Under Both The Pre-1992 And Post-1992 Materiality Standard 26

B. The Boneau Prior Art Was Material To The Lau '167, '168 and '133 Patents Under Both The Pre-1992 And Post-1992 Materiality Standard 28

C. ACS Has Not Shown, And Cannot Show, That The Boneau Prior Art Would Have Been Cumulative Or Non-Material 29

D. ACS's Own Words And Conduct Confirms The Materiality Of The Boneau Information 31

IV. THE EVIDENCE CLEARLY AND CONVINCINGLY ESTABLISHES ACS'S INTENT TO DECEIVE THE PTO 32

A. ACS's Conduct Shows That, With Respect To The Boneau Prior Art, From The Very Beginning, ACS Was Engaged In Deception 33

B.	ACS's Intent To Deceive Is Clear From The Prior Art That It Did Disclose To The PTO	34
C.	ACS's Partial Disclosure Of The Boneau Prior Art In August 1997 Shows Intent To Deceive	35
D.	ACS's Failure To Offer Any Evidence Of Good Faith Establishes ACS's Intent To Mislead The PTO	35
E.	ACS Cannot Overcome Its Failure To Offer Evidence Of Good Faith	36
F.	ACS's Collective "Corporate Amnesia" Shows Its Intent To Deceive The PTO	37
G.	ACS's Intent To Deceive Can Be Inferred From Its Failure To Call Key Witnesses	39
H	The Evidence Of ACS's Intent To Deceive The PTO Is More Than Clear And Convincing – It Is Overwhelming And Unrefuted	39
CONCLUSION		40

TABLE OF CITATIONS

Cases

A.B. Dick Co. v. Burroughs Corp.,
798 F.2d 1392 (Fed. Cir. 1986) 39

Atofina v. Great Lakes Chem. Corp.,
2005 U.S. Dist. LEXIS 7365 (D. Del. Mar. 16, 2005) 25

Baxter Int'l, Inc. v. McGaw, Inc.,
149 F.3d 1321 (Fed. Cir. 1998) 22, 28, 32

Brasseler, USA I, L.P. v. Stryker Sales Corp.,
267 F.3d 1370 (Fed. Cir. 2001) 19, 22, 24

Consolidated Alum. Corp. v. Foseco Int'l Ltd.,
910 F.2d 804 (Fed. Cir. 1990) 22

D.O.C.C., Inc. v. Spintech, Inc.,
36 U.S.P.Q.2d 1145 (S.D.N.Y. 1994) 33

Dayco Prods., Inc. v. Total Containment, Inc.,
329 F.3d 1358 (Fed. Cir. 2003) 25, 26

FMC Corp. v. Manitowoc Co.,
835 F.2d 1411 (Fed. Cir. 1987) *passim*

Fox Indus., Inc. v. Structural Preservation Sys., Inc.,
922 F.2d 801 (Fed. Cir. 1990) 21, 22

Gardco Mfg., Inc. v. Herst Lighting Co.,
820 F.2d 1209 (Fed. Cir. 1987) 25

J.P. Stevens & Co. v. Lex Tex, Ltd.,
747 F.2d 1553 (Fed. Cir. 1984) 33

Kingsdown Med. Consultants v. Hollister, Inc.,
863 F.2d 867 (Fed. Cir. 1988) 22

Kingsland v. Dorsey,
338 U.S. 318 (1949) 21

LaBounty Mfg., Inc. v. ITC,
958 F.2d 1066 (Fed. Cir. 1992) 25, 32

Li Second Family Ltd. v. Toshiba Corp.,
231 F.3d 1373 (Fed. Cir. 2000) 21

Molins PLC v. Textron, Inc.,
48 F.3d 1172 (Fed. Cir. 1995) 21

Paragon Podiatry Lab. Inc, v. KLM Lab., Inc.,
984 F.2d 1182 (Fed. Cir. 1993) 35

PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.,
225 F.3d 1315 (Fed. Cir. 2000) 22

Precision Instrument Mfg. Co. v. Automative Maint. Mach. Co.,
324 U.S. 806 (1945) 21

Rohm & Haas Co. v. Crystal Chemical Co.,
722 F.2d 1556 (Fed. Cir. 1983) 32

Semiconductor Energy Lab. v. Samsung Elecs.,
204 F.3d 1368 (Fed. Cir. 2000) 28, 32, 33

Statutes

37 C.F.R. §1.131(a) 30

37 C.F.R. §1.56 *passim*

Fed. R. Evid. 401-406 36, 37

MPEP §2001 *passim*

MPEP §2004 25

NATURE AND STAGE OF PROCEEDINGS

Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation (collectively, "ACS") sued Medtronic Vascular, Inc. and Medtronic USA, Inc. (collectively, "Medtronic") alleging that various Medtronic stent products infringe certain claims of ACS's "Lau patents."[1] Medtronic maintained that the Lau patents are not infringed, are invalid, and are unenforceable. At the trial on infringement and invalidity held February 7 to 18, 2005, a jury found the Lau patents infringed and not invalid. (D.I. 629).

On June 7 and 8, 2005, the Court held a bench trial on Medtronic's inequitable conduct claim. This is Medtronic's opening post-trial brief on that claim.

SUMMARY OF ARGUMENT

To hold a patent unenforceable for inequitable conduct, a court must find that: (1) one or more individuals involved in the prosecution of the patent knew about prior art but did not disclose it to the Patent and Trademark Office ("PTO"); (2) the prior art was material to at least one claim in the application; and (3) the prior art was withheld with an intent to mislead the PTO. Seldom has there been a case where the evidence of inequitable conduct on these points is more compelling than here.

There is no question that individuals substantively involved in the prosecution of the Lau patents knew just about everything there was to know about the Boneau prior art. The Boneau prior art included not only the information in Michael Boneau's patent application, but also other details of Mr. Boneau's stent work. ACS's prosecuting attorney, Edward Lynch, reviewed the Boneau application multiple times in January and March 1990 and would have learned, among other things, that the application disclosed a design wherein the stent is a sinusoidal ring and has a length less than its diameter (the "L<D" relationship). ACS's inventor, Lilip Lau, also had extensive knowledge of the Boneau prior art. In July 1990, Mr. Lau knew so much about the Boneau stent that he was able to write a report about it, rating it

[1] ACS asserted claims 1, 4, and 12 of U.S. Patent No. 5,512,154; claims 5 and 8 of U.S. Patent No. 6,066,167; claims 1, 3, and 11 of U.S. Patent No. 6,066,168; and claims 1, 2, 3, and 9 of U.S. Patent No. 6,432,133. "Lau patents" refers to these patents, and, if appropriate in context, other patents issuing from the original Lau application (Ser. No. 07/783,558). The accused products are Medtronic's MicroStent II, GFX, GFX2, GFX 2.5, S540, S660, S670, S7, BeStent2, Driver, MicroDriver, and Racer stents.

according to seventeen separate attributes. Starting in August 1990, Mr. Lau also attended a series of meetings with Dr. Simon Stertzer and Mr. Boneau during which he learned information beyond what was disclosed in the Boneau application, including the use of multiple Boneau stents aligned crown-to-crown or "out of phase," as well as Mr. Boneau's idea of connecting multiple Boneau stents together.

Similarly, there is no question that ACS failed to timely and fully disclose the Boneau prior art to the PTO, even though the claims of the Lau patents contain many of the elements disclosed in the Boneau prior art. ACS withheld the Boneau prior art completely for six years while prosecuting the first of the Lau patents in issue in this case (the '154 patent). Then, in August 1997, for reasons it has failed to explain, ACS disclosed some, but not all, of the Boneau prior art, informing the PTO of the Boneau '331 patent, which issued from the Boneau application. Even then, though, ACS failed to disclose other aspects of the Boneau prior art, including the out-of-phase arrangement and connections. It is believed that ACS continues to this day to conceal that information from the PTO in connection with pending continuation and divisional Lau applications.

Next, there is no question that the Boneau prior art was material to the prosecution of the Lau patents because it discloses key features claimed in the Lau patents. The Lau '154 patent essentially claims a stent with multiple sinusoidal rings, each with a length less than its diameter, connected together. Certain claims of the Lau '167, '168, and '133 patents add that the rings are aligned out of phase. The Boneau prior art disclosed multiple sinusoidal rings, the L<D relationship, an out of phase arrangement, and connections. Given these similarities, the Boneau prior art was highly material and was not cumulative to any of the prior art before the PTO.

There is also no question that the individuals substantively involved in the prosecution of the Lau patents knew (or should have known) the Boneau prior art was material. In 1997, ACS's patent attorney admitted as much when he twice told the PTO that at least a part of the Boneau prior art (the Boneau '331 patent) was "relevant" to the Lau applications. Moreover, the Boneau prior art was so material that the Boneau application was the first prior art reference that ACS had its patent attorney review after Mr. Lau conceived his "invention." Even ACS's engineer, Farhad Khosravi, recognized the importance of Boneau; he testified that if ACS would have cut Boneau stents out of a tube and spaced them close

together, they would essentially be the stents claimed in the Lau patents.

Given the overwhelming evidence of knowledge and materiality, it must be inferred that ACS intended to deceive the PTO. Medtronic has established a prima facie case of materiality of the known but undisclosed prior art, which shifts the burden to ACS to show that it acted in good faith. ACS has completely failed to do so. Instead of coming forward with evidence of what those involved in the prosecution of the Lau patents were thinking when they chose not to timely and fully disclose the Boneau prior art, ACS concealed such evidence by steadfastly asserting the attorney-client privilege. By doing so, ACS deprived the Court of the only direct evidence on why the ACS individuals decided to withhold the Boneau prior art from the PTO until 1997 – six years after the initial Lau patent application was filed – and then to make only a partial disclosure of the Boneau prior art. ACS has decided that, strategically, it is better to conceal this information from the Court than to disclose it. Balancing the materiality and extent of ACS's knowledge of the Boneau prior art against the complete lack of evidence of good faith on ACS's part compels the conclusion ACS committed inequitable conduct.

ACS's deception of the PTO was part of a larger pattern of deception and intentionally withholding information about the Boneau stent. First, ACS feigned interest in the Boneau stent, encouraging Mr. Boneau and Dr. Stertzer to disclose more and more information so it could learn all there was to know about their design. At the same time, ACS concealed from them that it had already evaluated the Boneau stent and decided to develop a very similar design. ACS has offered no rational explanation to justify this deception. Second, ACS intentionally withheld information from the PTO. Third, at trial, ACS intentionally withheld information from the Court by asserting the attorney-client privilege even though the burden was on it to come forward with evidence of its good faith. If ACS is allowed to avoid the consequences of its actions by simply withholding information, it will have created a template for any patentee to avoid answering for its inequitable conduct: assert the privilege and then argue that the resulting lack of direct evidence as to state of mind constitutes a failure of proof. A holding of inequitable conduct is inescapable where, as here, ACS has the key to explaining how it could have possibly acted in good faith in view of the overwhelming evidence of knowledge and materiality, but decides not to use it.

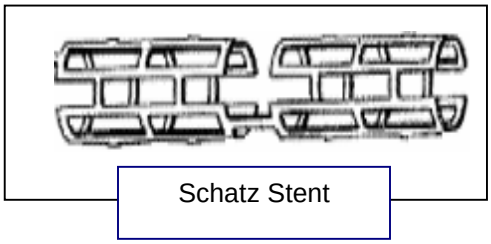
PROPOSED FINDINGS OF FACT

A. Certain Relevant Prior Art

1. Palmaz '417 ("Spiral Palmaz Patent"): On March 28, 1988, Dr. Palmaz filed U.S. Application No. 174,246, entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft." (AX-160). On April 7, 1992, the application issued as U.S. Patent No. 5,102,417). (*Id.*). The Spiral Palmaz patent discloses a stent consisting of three shorter, single-slotted Palmaz stents connected by spiral-shaped connectors. (D.I. 633, Tr. at 391:19-392:10, 393:9-393:15; D.I. 636, Tr. at 1263:15-20; AX-160).

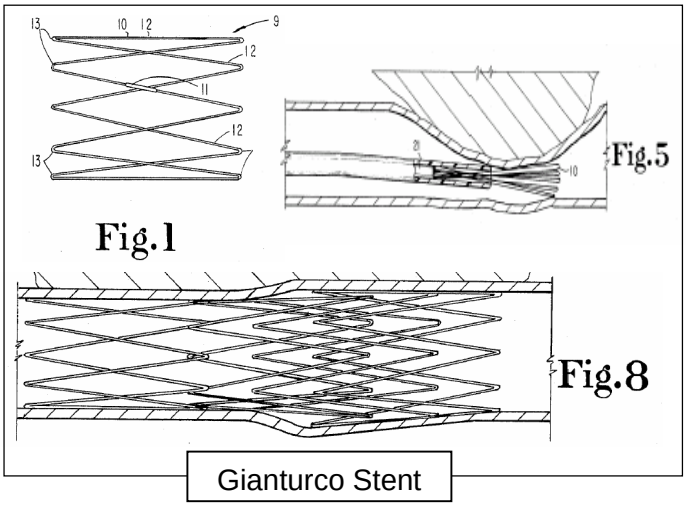
Spiral Palmaz

2. Schatz '984 Patent: On October 4, 1988, Dr. Richard Schatz filed U.S. Application No. 253,115, and on February 19, 1991, filed continuation application No. 657,296 on an "Expandable Intraluminal Graft." (AX-54). The continuation application issued as U.S. Patent No. 5,195,984. (*Id.*). The Schatz '984 patent discloses a stent made of a series of shortened Palmaz stents connected together. (D.I. 636, Tr. at 1263:3-8; AX-54). The Palmaz-Schatz stent, which embodied the Schatz patent, consisted of a number of 7-millimeter Palmaz stents connected together. (D.I. 636, Tr. at 1262:20-1263:11).



Schatz Stent

3. Gianturco '568 Patent: On October 1, 1984, Dr. Cesare Gianturco filed U.S. Application No. 656,261, entitled "Percutaneous Endovascular Stent And Method For Insertion Thereof," which issued on April 8, 1986 as U.S. Patent No. 4,580,568. (AX-40). The Gianturco patent discloses a self-expanding, zigzag-shaped stent made of a two-piece ring connected together by a sleeve. The stent is compressed into a sheath and springs open upon delivery. (D.I. 670, Tr. at 173:17-174:19, 192:17-21;

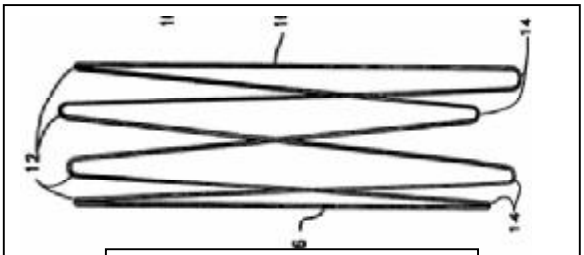


Gianturco Stent

AX 40). Figure 1 (showing the stent) and Figure 5 (showing the stent compressed into the sheath) of the Gianturco patent are reproduced above. The Gianturco Z stent, which was the commercial embodiment of the Gianturco patent, was 25 millimeters long. (D.I. 637, Tr. at 1555:11-1556:3). The Gianturco patent also discloses the use of multiple stents, implanted individually and overlapping one another. (AX-40). Figure 8 of the Gianturco patent (above) illustrates the overlapping stents.

4. The Boneau Prior Art: In October 1988, Michael Boneau invented the Boneau stent: a balloon-expandable, plastically deformable, sinusoidal-shaped device made of a single wire that could be made in varying lengths and diameters and was delivered – either singly or in multiples – crimped on a single balloon catheter. (D.I. 543 at 3; D.I. 636, Tr. at 1210:21-1213:3).[2] There are important differences between the Boneau stent and the Gianturco stent: whereas the Gianturco stent was self-expanding, Mr. Boneau's stent is balloon expandable and plastically deformable; unlike Gianturco, the Boneau stent is made from a single-piece ring; Gianturco had to compress his stent into a sheath for delivery, whereas the Boneau stent is crimped directly onto a balloon; although the Gianturco patent does not disclose a range of sizes, Boneau did, including where the length of the stent was less than its diameter; and Gianturco disclosed the use of multiple stents implanted individually and overlapping each other, whereas Boneau disclosed the use of multiple stents implanted simultaneously and not overlapping each other. (D.I. 670, Tr. at 174:3-19; AX-18; AX-40). In an internal ACS study of both Gianturco and Boneau, ACS conceded that Boneau was a "novel stent design." (D.I. 671, Tr. at 417:25-419:18; DTX-1579).

5. On August 24, 1989, Mr. Boneau filed U.S. Application No. 07/398,180, entitled "Endovascular Support Device." (D.I. 664, Ex. 1, Fact 3; AX-18; D.I. 670, Tr. at 115:17-116:2, 119:19-25; DTX-1005) (the "Boneau application"). On March 8, 1994, the Boneau application issued as U.S. Patent No. 5,292,331 (Figure 1 of which is pictured here) (the "Boneau



Boneau Patent, Fig. 1

[2] ACS has suggested that the Boneau stent was similar to, the same as, or obvious in view of the Gianturco patent. The court, however, denied ACS's motion for summary judgment that the Boneau patent was anticipated by the Gianturco patent. (D.I. 546).

patent"). (D.I. 664, Ex. 1, Fact 4; AX-18) The Boneau patent states:

> Typical cardiovascular vessels into which the stent [] might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding *stents may range from one millimeter to two centimeters* in length.
>
> * * * *
>
> One of the advantages of the stent [] is that *multiple stents* may be used in the treatment of a single lesion. . . . . In instances where it is known in advance that multiple stents will be the preferred method of treatment, *a plurality of such stents* may be *positioned along a single balloon catheter* for simultaneous delivery to the affected area.

(AX-18 at col. 5, lines 25-29 & col. 6, lines 27-41) (emphasis added). Thus, although the figures of the Boneau patent reveal only a single stent having a relatively long length, the Boneau patent discloses more broadly the use of multiple stents, each having a length less than its diameter, and indeed, as short as one millimeter. (D.I. 670, Tr. at 167:13-168:20; AX-18 at col. 5, lines 25-29).

6. Beginning in 1988, Mr. Boneau made and bench-tested Boneau stents of various sizes, including stents as short as 2.2 millimeters. (D.I. 670, Tr. at 108:10-113:12; 117:14-119:25; DTX-1319). Both the Boneau application and Mr. Boneau's manufacturing specification documents show this. (AX-18; DTX-1005; DTX-1319). Mr. Boneau tested stents of various lengths because he knew that arteries in men and women tend to be of different sizes, with women's arteries typically being smaller. (D.I. 670, Tr. at 112:12-113:6).

7. Also in 1988, Mr. Boneau began working with Dr. Stertzer, a pioneer in the field of interventional cardiology and the first man to implant a stent in a human being in the United States. (*Id.* at 36:1-22). Recognizing the potential of Mr. Boneau's stent, in 1988, Dr. Stertzer began testing and successfully implanting Boneau stents in human patients, in the U.S. and abroad. (*Id.* at 34:21-36:22; 40:9-41:15; 46:2-19). His clinical work included implanting multiple Boneau stents in a single artery (*id.* at 41:16-18), making sure to align them crown-to-crown ("out of phase") to avoid significant gaps between the stents that could cause restenosis. (*Id.* at 41:19-45:24; DTX-495).

8. By August 1988, based on the disclosure in the Boneau application and the work done by Mr. Boneau and Dr. Stertzer, the scope of the Boneau prior art included the use of multiple Boneau stents, each with a length less than its diameter, and the crown-to-crown alignment of stents. (*See* Findings 4-7).

9. In March 1990, Mr. Boneau conceived of taking multiple Boneau stents and connecting

them together using sutures (again, in a crown-to-crown configuration). (D.I. 670 at 136:22-138:18). In around March or April 1990, Mr. Boneau conducted bench-testing on multiple connected Boneau stents. (*Id.* at 138:5-18). Mr. Boneau did not, however, file for a patent on the concept at that time. (*Id.* at 162:22-163:4 (explaining he was distracted during that timeframe due to personal problems)).

B. ACS's Knowledge Of The Boneau Prior Art

10. Despite their successes, Mr. Boneau and Dr. Stertzer did not have the resources needed to commercialize the Boneau technology. (*Id.* at 65:15-25; 100:6-14). Thus, they sought to engage a medical device company to take over the development of that technology. (*Id.* at 65:6-22).[3]

11. Spring 1989: Beginning in the Spring of 1989, Dr. Stertzer – at the time a consultant for ACS – began discussing the Boneau stent with senior-level representatives at ACS, including Ron Dollens, Carl Simpson, Elizabeth McDermott, and Michael Orth. (*Id.* at 61:11-62:11). Mr. Dollens was President and CEO of ACS (D.I. 632, Tr. at 324:2-6; D.I. 670, Tr. at 62:18-24); Mr. Simpson was Senior Vice President of Research and Development (D.I. 671, Tr. at 306:21-307:9); Ms. McDermott was Director of Research and Development (D.I. 670, Tr. at 63:9-17, 262:2-16); and Mr. Orth was the Business Manager of ACS's Stent Business Unit. (D.I. 671, Tr. at 382:12-23).

12. In about May 1989, Mr. Boneau began discussing his stent with other senior-level ACS representatives, including Wilfred Samson and Gary Schneiderman. (D.I. 670, Tr. at 113:13-115:13). Mr. Samson was Vice President of Research and Development, and Dr. Schneiderman was Director of Research and Development. (*Id.*). Mr. Boneau showed them a prototype of the Boneau stent and also discussed with them the properties of the stent, as well as issues of patentability. (*Id.*).

13. July 1989: In July 1989, while Mr. Boneau and Dr. Stertzer were still discussing the Boneau stent with ACS, ACS hired Mr. Lau, fresh out of college, to work as a stent engineer. (D.I. 670, Tr. at 263:22-264:20; D.I. 671, Tr. at 424:12-13). During Mr. Lau's first year at ACS, Ms. McDermott was his supervisor, and he reported directly to her. (D.I. 670, Tr. at 264:21-265:4; D.I. 671, Tr. at 424:16-

[3] For the Court's convenience, two graphics summarizing the sequence of events discussed in detail below from the Spring of 1989 to the fall of 1990 are attached. Exhibit A was presented as a demonstrative during the July 7-8 trial. Exhibit B is a more detailed presentation, citing to key evidence.

22; 497:17-23). On his first day of work, Ms. McDermott assigned Mr. Lau to begin working on stent development. From there on, the two met about twice a week to discuss his stent work and to brainstorm ideas. (D.I. 671, Tr. at 424:16-19; 498:7-17).

14. August 1989: In August 1989, at Dr. Schneiderman's request, Mr. Boneau provided Dr. Schneiderman with a copy of the Boneau application. The two also discussed Dr. Stertzer's clinical work with the Boneau stent. (D.I. 670, Tr. at 115:17-116:24; DTX-798).

15. September 1989: In September 1989, Dr. Schneiderman told Mr. Boneau that ACS was not interested in pursuing the Boneau stent, and, indeed, that ACS would never pursue a metal stent to implant in a human artery. (*Id.* at 116:25-117:12).[4] Dr. Schneiderman made this representation even though ACS had Mr. Lau and others working on metal stent designs at around that same time. (D.I. 671, Tr. at 386:13-22).

16. January 1990: In January 1990, months after ACS told Mr. Boneau it was not interested in the Boneau stent, Mr. Samson instructed ACS's in-house patent counsel, Bruce Barclay, to have ACS's outside patent counsel, Edward Lynch, review the Boneau application. (D.I. 670, Tr. at 213:22-215:1). Without asking Mr. Boneau's permission, Mr. Barclay contacted Mr. Lynch and forwarded him a copy of the Boneau application for his review. (*Id.* at 105:1-6, 214:221-215:1, 234:7-237:13, 258:13-24; DTX-1008, DTX-1009 & DTX-1010).

17. In mid-January 1990, as Mr. Barclay requested, Mr. Lynch reviewed the Boneau application. (*Id.* at 229:9-13, 230:14-17, 234:7-238:19, 258:13-24, D.I. 671, Tr. at 548:17-549:1; DTX-1008, DTX-1009 & DTX-1010).[5] Mr. Lynch's billing records show that, on January 15, 1990, he spent 2 hours, and on January 17, 1990, he spent another 2.5 hours reviewing the application and preparing a report relating to his review. (DTX-1008). ACS's privilege log shows that Mr. Lynch sent Mr. Barclay a report dated January 17, 1990 relating to the Boneau application. (D.I. 670, Tr. at 259:2-25; DTX-1163).

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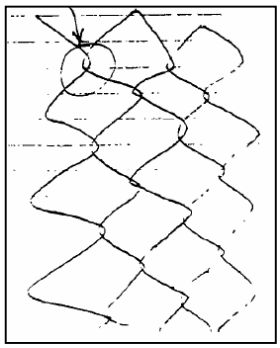
[4] Although Dr. Schneiderman attended both the liability trial and the inequitable conduct trial, ACS did not call him as a witness to refute any of Mr. Boneau's testimony.

[5] Mr. Lynch referred to the Boneau application as the "ESS application;" ESS being an acronym for Mr. Boneau's company, Endothelial Support Systems.

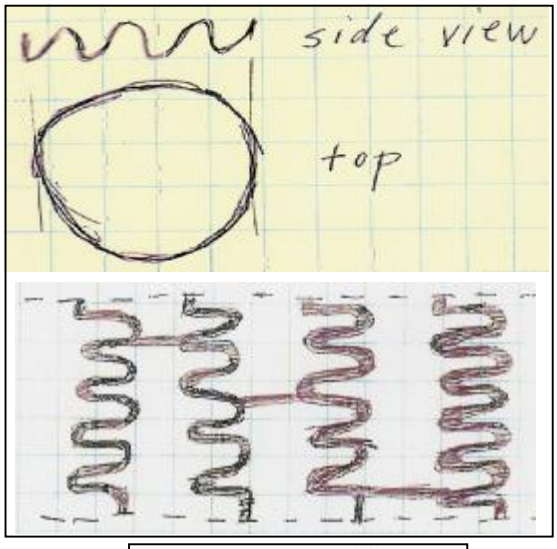
ACS refused to produce Mr. Lynch's report or to allow Medtronic to ask Mr. Lynch questions about the contents of the report, asserting attorney-client privilege. (D.I. 670, Tr. at 221:25-222:18, 230:2-13, 259:2-9).

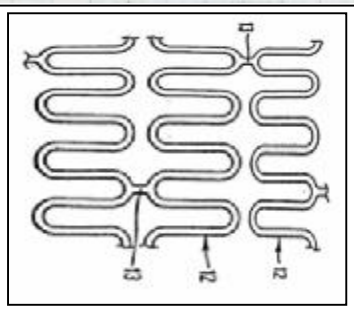
18. Because ACS asserted the privilege, there is no direct evidence of: (a) why ACS asked Mr. Lynch to review the Boneau application; (b) Mr. Lynch's mental impressions based on his review; (c) the contents of Mr. Lynch's report; or (d) the advice he provided to ACS regarding the Boneau prior art. Clearly, however, in January 1990, ACS was interested in, or had some concern about, the Boneau stent.

19. On January 17, 1990, the *same day* Mr. Lynch sent his report to Mr. Barclay, and eight months after Mr. Boneau initially disclosed the Boneau stent to ACS, Mr. Lau claims to have reached one of the "milestones" in the conception of his invention, namely the idea of a stent consisting of a series of sinusoidal or zigzag-shaped elements, what Mr. Lau referred to as a "chain link design" (pictured at right). (D.I. 671, Tr. at 439:2-9, 446:3-448:1; AX-798).



20. March 1990: On Friday, March 2, 1990, Mr. Lau claims to have reached the final "milestone" in the conception of his invention, which included using individual sinusoidal or zigzag-shaped rings or "hoops" and connecting them together. (D.I. 671, Tr. at 450:24-452:21, 455:19-456:16; AX-799). On that date, Mr. Lau drew pictures in his lab notebook (at left) of the zigzag-shaped rings and the rings being connected. Mr. Lau later used a computer to draw a picture showing the individual zigzag-shaped rings connected together in a crown-to-crown configuration, shown to the left.





21. Mr. Lau initially called his design the zigzag rings design. (D.I. 671, Tr. at 466:24-468:1). It

later became known as the "Bronco" stent, and ACS's commercial embodiment of Mr. Lau's alleged invention became known as ACS's Multilink stent. (D.I. 671, Tr. at 393:10-18, 502:22-503:7).

22. By Friday, March 9, 1990, only days after Mr. Lau purportedly came up with his connected zigzag ring design, Mr. Lynch had contacted James Eakin, the attorney prosecuting the Boneau application, and asked Mr. Eakin to send him a second copy of the Boneau application. (DTX-1012). Mr. Eakin sent Mr. Lynch the second copy on March 9, 1990 by Federal Express. (*Id.*).

23. Mr. Lynch testified that by Monday, March 12, 1990, he had received and reviewed the second copy of the Boneau application. (*Id.* at 230:25-232:5, 237:14-240:3; DTX-1010). Mr. Lynch's billing records show that on Monday, March 12, 1990, he spent 2.5 hours reviewing the Boneau application and called Ms. McDermott to discuss his review. (DTX-1010). Mr. Lynch testified that it must have been Ms. McDermott he spoke to because the Boneau application related to something in which she was involved. (*Id.* at 241:4-12).

24. Because ACS asserted the privilege, there is no direct testimony of why ACS wanted Mr. Lynch to conduct a second review of the Boneau application, of Mr. Lynch's mental impressions from his second review, or of what Mr. Lynch told Ms. McDermott about the Boneau application and Mr. Lau's invention. The circumstantial evidence, however, compels the conclusion that on or about Friday, March 2, 1990, Mr. Lau reported his invention to Ms. McDermott and that by Friday, March 9, 1990, Ms. McDermott, who was aware of the Boneau application, was concerned that either Mr. Lau's design would infringe whatever patent issued from the Boneau application or Mr. Lau's design would not be patentable in view of Boneau. Thus, Ms. McDermott contacted Mr. Lynch and asked him to review the Boneau application again and to provide her with an opinion, presumably on infringement and/or patentability. Mr. Lynch evidently sought the second copy of the Boneau application to ensure he had the version actually filed with the PTO. On Monday, March 12, 1990, Mr. Lynch received and again reviewed the Boneau application. On that same day, he contacted Ms. McDermott and gave her his opinions.

25. Sometime in mid-1990, Mr. Lau and ACS's Business Manager for Stents, Farhad Khosravi, began analyzing and comparing ten stents they considered to be the most promising stent designs of the time: "five leading competitive stent designs" and five of ACS's own designs. (D.I. 670,

Tr. at 282:1-11; D.I. 671, Tr. at 387:24-389:8, 500:6-502:10, 503:18-504:20; AX-268; DTX-1014). Mr. Lau and Mr. Khosravi undertook the project at the direction of Mr. Khosravi's supervisor, Mr. Orth. (D.I. 671, Tr. at 402:18-403:1, 406:24-407:2). They intended their analysis to help ACS decide which stent to develop to bring to market. (*Id.* at 388:7-389:11, 462:18-25). In July 1990, Mr. Lau and Mr. Khosravi issued a report detailing their analysis ("Bronco report"). (DTX-1014; AX-268). The report ranked each of the stents from "poor" to "superior" based on 17 separate stent attributes, (D.I. 671, Tr. at 512:3-24; DTX-1014; AX-268), and recommended that ACS develop Mr. Lau's zigzag rings stent. (D.I. 671, Tr. at 393:12-18, 499:23-500:5; DTX 1014 at 3).

26. Included in the report among the "five leading competitive stents" was the Boneau stent, which Mr. Lau and Mr. Khosravi described as having a "[s]hort tubular structure, <10 mm, wound from a single lengthwise zigzagging metal wire" and being "[b]alloon expandable achieving enlargement by plastic deformation." (DTX-1014 at ACS242618). Mr. Lau testified that, at the time, he also knew that the Boneau stent was mounted on a PTCA balloon. (D.I. 671, Tr. at 511:7-9). Mr. Lau and Mr. Khosravi also included a sketch of a Boneau stent in the report. (DTX-1014 at ACS242618). They ranked the Boneau stent "superior" in terms of technical feasibility, luminal protrusion, and wall contact. (D.I. 671, Tr. at 513:15-514:4; DTX-1014; AX-268).

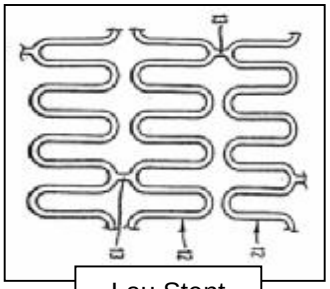
27. Although the authors of the Bronco report had enough information about the Boneau stent to rank it in terms of 17 separate attributes, Mr. Lau and Mr. Orth both testified that they did not know much about the Boneau stent at that time. (D.I. 671, Tr. at 390:12-391:8, 468:2-469:22). Both men also testified that they had no recollection of how they obtained the information in the report or how they were able to assign 17 specific rankings to the Boneau stent. (*Id.* at 413:16-414:3, 505:2-11). It is reasonable to conclude that Mr. Lau had access to the Boneau application, either directly or indirectly, through Ms. McDermott. Mr. Lau testified that he met with Ms. McDermott routinely to discuss stents and that she shared information with him about prior art stents. (*Id.* at 424:16-425:10, 498:7-17). This is not surprising given that Mr. Lau had just recently graduated college and had no prior stent experience. Given the nature and frequency of the contacts between Ms. McDermott and Mr. Lau, and because information about the Boneau stent was not publicly available at that time (and, indeed, could have come

only from the Boneau application), the only reasonable inference is that Mr. Lau learned the information from Ms. McDermott.

28. One of the five "ACS internal designs" included in the Bronco report was Mr. Lau's zigzag rings stent, which Mr. Lau and Mr. Khosravi described as having a "[f]lexible interconnected zigzagging ring structure, etched from a metal tube" and being "[b]alloon expandable achieving enlargement of diameter by plastic deformation, crimped onto PTCA balloon." (D.I. 671, Tr. at 466:24-468:1; DTX-1014 at ACS242623).

29. Thus, in the July 1990 Bronco report, Mr. Lau described the Boneau stent and his own stent in similar terms as having a zigzagging design, being balloon expandable, plastically deformable, and mounted on a PTCA balloon. (DTX-1014, AX-268). Moreover, the Boneau prior art and Mr. Lau's stent were quite similar in shape and structure. As shown in the picture below, the slight difference between the Boneau stent and Mr. Lau's design is the addition of connections between the sinusoidal-shaped rings. Mr. Khosravi, who was part of the team that assisted Mr. Lau in developing his stent, testified that, in his view, "if you make the . . . Boneau out of a tube, make the segments short enough, have the number of segments closely enough connected to each other, then effectively, it's a Bronco stent." (D.I. 670, Tr. at 283:22-284:10, 289:1-7).

Multiple Boneau Stents on Balloon



Lau Stent

30. July-September 1990: In July 1990, despite having previously told Mr. Boneau that it was not interested in his stent, and although Mr. Lau had already recommended pursuing his own stent design, Mr. Simpson contacted Mr. Boneau and told him that ACS had a renewed interest in the Boneau stent. (*Id.* at 120:2-121:15, 122:24-123:4; DTX-0076).[6]

[6] Although Mr. Boneau confirmed the conversation setting up this meeting in writing, Mr. Simpson claimed he did not recall the conversation or ever having an interest in the Boneau stent. (D.I. 671, Tr. at 312:5-313:4). Mr. Simpson conceded having discussions with Mr. Boneau and Dr. Stertzer about the (continued . . .)

31. In about August or September 1990, responding to ACS's request, Mr. Boneau and Dr. Stertzer traveled to ACS's corporate offices and made a formal presentation on the Boneau stent to a group of senior ACS representatives. (D.I. 670, Tr. at 63:24-67:16, 122:21-123:8). The group included at least Mr. Lau, Ms. McDermott, Mr. Orth, and Mr. Khosravi. (*Id.* at 64:9-65:4, 123:9-21, 284:21-285:13, 286:10-24). During the presentation, Mr. Boneau and Dr. Stertzer candidly disclosed all of the information they had about the Boneau stent, including clinical data and angiograph pictures showing multiple Boneau stents implanted in a single artery in a crown-to-crown (or "out of phase") configuration. (*Id.* at 66:9-67:16, 123:22-125:15, 135:13-17, 286:10-24; D.I. 671, Tr. at 397:6-14).[7]

32. In the same timeframe, Mr. Boneau had three more meetings with Mr. Lau, Mr. Orth, and Mr. Khosravi to discuss the Boneau stent. (*Id.* at 125:20-126:2; D.I. 671, Tr. at 416:11-17). During those meetings, Mr. Boneau provided prototypes of the Boneau stent, photographs of multiple Boneau stents both mounted on a balloon in a crown-to-crown or "out of phase" configuration and implanted in an artery. (D.I. 670, Tr. at 126:3-134:24, 140:1-8; DTX-227; DTX-482; DTX-495; DTX-497). Mr. Boneau detailed the physical characteristics of the Boneau stent for Mr. Lau and the other ACS engineers and told them how he made the stent, the importance of implanting multiple stents in a crown-to-crown or "out of phase" configuration, and that he had been working with the stent since 1988. (D.I. 670, Tr. at 104:5-25, 126:3-134:24, 140:1-8; DTX-227; DTX-482; DTX-495; DTX-497). Mr. Boneau also told them that he had previously come up with the idea of connecting multiple Boneau rings, crown-to-crown, with sutures. (D.I. 670, Tr. at 136:24-138:18). Mr. Boneau testified that, after these meetings, Mr. Lau and the other

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(. . . continued)
Boneau stent, but claimed he did not recall ever knowing anything about the structure of the Boneau stent. (*Id.* at 308:8-312:4; 314:9-21). This testimony is not credible. Based on the timeline of events, the only logical explanation is that ACS invited Mr. Boneau back because ACS recognized the similarities between Mr. Boneau's design and Mr. Lau's design and wanted as much information about the Boneau stent as possible either to develop its own stent, to determine whether Mr. Lau's design would be patentable, or to determine whether Mr. Lau's design would infringe should a Boneau patent issue.

[7] Mr. Orth did not deny that this information was shared, but rather that he did not recall it being shared. (D.I. 671, Tr. at 400:12-19; 417:14-24). Mr. Lau similarly did not deny that this information was shared, but only that he did not recall Dr. Stertzer or Mr. Boneau presenting clinical data or discussing implanting stents in a crown-to-crown configuration. (*Id.* at 481:17-21; 520:15-19).

ACS engineers "knew as much about, and probably more . . . about making the Boneau stent and using the Boneau stent than I did." (*Id.* at 126:3-127:2).

33. The ACS representatives never told Mr. Boneau or Dr. Stertzer that Mr. Lau had already analyzed the Boneau stent and recommended that ACS pursue Lau's zigzag rings stent, not the Boneau stent. (*Id.* at 67:17-68:11, 104:17-20; D.I. 671, Tr. at 417:3-13). They also never told Mr. Boneau or Dr. Stertzer that ACS was already working on its own stent. (D.I. 670, Tr. at 104:17-20, 135:18-136:21).[8] Dr. Stertzer testified that he would not have shared information related to the Boneau stent, let alone all of the information they had, if he knew ACS was working on its own stent and had already decided not to pursue the Boneau stent. (*Id.* at 67:17-68:11).

34. After the meetings with Mr. Boneau and Dr. Stertzer, Mr. Orth told Mr. Lau and Mr. Khosravi to test the prototype Boneau stents Mr. Boneau had provided. (D.I. 671, Tr. at 402:14-403:1). Mr. Lau and Mr. Khosravi took Scanning Electron Microscope pictures of the stents, bench-tested them, and measured them. (*Id.* at 416:18-417:2, 520:20-521:9). Mr. Orth then reported to Ms. McDermott about the meetings with Mr. Boneau and their evaluation of his prototypes. (*Id.* at 411:19-412:4).

35. In September 1990, after meeting with Mr. Boneau and Dr. Stertzer, having gathered all the information about the Boneau stent they could, ACS again advised Mr. Boneau that it was not interested in pursuing the Boneau stent. (*Id.* at 405:18-406:5).[9]

C. The Lau Patents

36. On September 4, 1990, while ACS was still meeting with Mr. Boneau and Dr. Stertzer, Mr. Barclay asked Mr. Lynch to start preparing patent applications on Mr. Lau's stent invention. (D.I.

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[8] Mr. Orth testified that he did not "conceal" these things from Mr. Boneau and Dr. Stertzer. (D.I. 671, Tr. at 397:15-21). Mr. Orth, however, did not testify that he told Mr. Boneau and/or Dr. Stertzer about ACS's internal stent development efforts either.

[9] Mr. Orth claimed the stents Mr. Boneau provided were of poor quality, even though acknowledging they were only prototypes. (D.I. 671, Tr. at 403:16-405:17). Mr. Orth failed to explain why, if the Boneau stents were of such poor quality, three of ACS's engineers, himself, Mr. Lau, and Mr. Khosravi, took time to meet with Mr. Boneau not once, but four separate times. Mr. Orth also did not explain why, if the Boneau stents were of such poor quality, in November 1991 (a month after the first Lau application was filed), he still referred to the Boneau stent as a competitive stent. (*Id.* at 414:17-415:24; DTX-1323).

670, Tr. at 259:2-260:3; DTX-1163).

37. On October 28, 1991, Mr. Lynch filed the initial Lau application, U.S. Application No. 07/783,558 to Lau, *et al.*, entitled "Expandable Stents and Method for Making Same." (AX-2586 at LJA 0091-1031). The '558 application as filed claimed Mr. Lau's invention broadly. Claim 1 covered:

> A longitudinally flexible stent, comprising a plurality of cylindrically shaped elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common axis."

(*Id.* at LJA-0115). The PTO rejected this and other pending claims in view of Spiral Palmaz. (*Id.* at LJA-0757).

38. Mr. Lynch prosecuted the '558 application from October 28, 1991 until October 1992, at which time John Nagy took over for him. (AX-2586 at LJA 0125-128, 151). While prosecuting this application, ACS disclosed over 100 prior art references, in the specification and in several Information Disclosure Statements. (*Id.* at LJA 0131-137). But, at no time did Mr. Lynch (or anyone from ACS) disclose any of the Boneau prior art to the PTO. (AX-2586 at LJA 0091-1031).

39. On December 9, 1993, Mr. Nagy filed U.S. Application No. 08/164,986, a continuation of the '558 application with similarly broad claims. (AX-2586 at LJA 0799). At no time during the prosecution of the '558 application did ACS disclose any of the Boneau prior art. On November 1, 1994, ACS abandoned the '558 application. (AX-2586 at LJA 0828).

40. On March 17, 1994, Mr. Nagy filed U.S. Application No. 08/214,402, a divisional of the '986 application. (AX-2586 at LJA 1034). At no time during the prosecution of the '986 application did ACS disclose any of the Boneau prior art. (AX-2586 at LJA 1033-1411). On June 6, 1995, the '986 application issued as U.S. Patent No. 5,421,955. (AX-2586 at LJA 0081).

41. On July 28, 1994, Mr. Nagy filed U.S. Application No. 08/281,790, a continuation of the '558 application. (AX-2586 at LJA 1412-1638). At no time during the prosecution of the '790 application did ACS disclose any of the Boneau prior art. (*Id.*). On May 7, 1996, the '790 application issued as U.S. Patent No. 5,514,154. (*Id.*; AX-1). All of the asserted claims of the '154 patent contain the "cylindrical element" limitation, which the Court construed as "a radially expandable segment of a stent having a longitudinal length less than its diameter with a circumferential undulating pattern." (D.I.

628 at 24). The Court construed the term "undulating pattern" to mean "a wavelike pattern." (*Id.* at 5). In addition, all of the claims of the Lau '154 patent require the "connecting elements" limitation.

42. On November 13, 1995, Mr. Nagy filed U.S. Application No. 08/556,516, a divisional of the '790 application. (AX-2586 at LJA 1640). At no time during the prosecution of the '516 application did ACS disclose any of the Boneau prior art. (AX-2586 at LJA 1639-1723). On February 18, 1997, the '516 application issued as U.S. Patent No. 5,603,721. (AX-2586 at LJA 0011). (Exhibit A mistakenly identifies this patent by its application number ('516) rather than its patent number ('721).)

43. On January 14, 1997, ACS filed U.S. Application Nos. 08/783,033 and 08/783,097, both continuations of the '558 application. (DTX-911; AX-2586 at LJA 1725-1832). On August 25, 1997, Mr. Nagy met with PTO examiner Chris Bennett. (DTX-911 at paper 7; AX-2586 at LJA 1790). In his interview summary, part of the '033 and '097 file histories, Mr. Bennett recorded that Mr. Nagy said he would be filing two prior art references that were "relevant to the claimed invention." (*Id.*). Mr. Nagy filed Amendments in each case in which he stated that examiner Bennett's interview summary "is accurate and requires no further explanation." (DTX-911, Amendment at 8; AX-2586 at LJA 1807). Along with the Amendments, Mr. Nagy filed a Supplemental Information Disclosure Statement ("IDS") disclosing two relevant prior art references, one of which was the Boneau patent. (DTX-911 at paper 9; AX-2586 at LJA 1802).

44. The record is silent as to why ACS decided to disclose the Boneau patent at this time or why ACS did not disclose the remaining Boneau prior art. On October 2, 1997, however, the PTO issued a Notice of Allowance indicating that the pending claims in the '097 application could be issued as a patent; on November 12, 1997, the PTO issued a Notice of Allowance indicating that the pending claims in the '033 application could be issued as a patent. On November 27, 1997, ACS filed this lawsuit against Medtronic. The '033 application issued as U.S. Patent No. 5,728,158 on March 17 (DTX-911), and the '097 application issued as U.S. Patent No. 5,735,893 (DTX-20) on April 7, 1998.

45. On May 26, 1998, Mr. Nagy filed U.S. Application No. 09/084,797 (AX-2586 at LJA 1953-2042), and on May 23, 2000, that application issued as U.S. Patent No. 6,066,167. (*Id.*; AX-5). All of the claims of the '167 patent require (a) "cylindrically shaped elements" (having the L<D relationship)

that are (b) "interconnected" and (c) "out of phase."

46. On April 6, 1998, Mr. Nagy filed U.S. Application No. 09/055,582 (AX-2586 at LJA 1833-1952), which issued as U.S. Patent No. 6,066,168 on May 23, 2000. (*Id.*; AX-6). All of the claims of the '168 patent require (a) "cylindrical elements" (including the L<D relationship) and (b) "connections." Claims 5-8 and 12-18 also require the elements to be "out of phase."

47. On November 16, 2000, Mr. Nagy filed U.S. Application No. 09/716,847 (AX-2586 at LJA 2323-2448), which issued August 13, 2002 as U.S. Patent No. 6,432,133. (*Id.*; AX-7). Claims 1-11 of the '133 patent require (a) "cylindrical elements" (and, therefore, the L<D relationship) and (b) "interconnections." Claim 11 of the '133 patent requires the elements to be "out of phase."

48. During the prosecution of the '167, '168, and '133 patents, ACS disclosed the Boneau patent, but never disclosed the remaining Boneau prior art, including the implantation of multiple Boneau stents in a crown-to-crown or "out of phase" configuration and the connection of multiple Boneau stents together with sutures. (AX-2586 at LJA 1412-1638, 1833-1952, 1953-2042, 2323-2448).

D. ACS's Unexplained Failure To Disclose The Boneau Prior Art

49. Mr. Lynch reviewed and analyzed the Boneau application in January and March 1990. (DTX-1008; DTX-1010). Subsequently, he began working on the initial Lau application and prepared and prosecuted the initial Lau application from October 1991 until October 1992. (D.I. 670, Tr. at 234:7-249:1; D.I. 671, Tr. at 243:22-244:18, 534:21-535:6; AX-8; DTX-1008, DTX-1009 & DTX-1010). Mr. Lynch testified that he did not recall, generally or specifically, any of his work relating to the initial Lau application. (D.I. 670, Tr. at 228:1-10). Mr. Lynch also claimed that he did not have any recollection at all, general or specific, of speaking with Mr. Lau, any of the other named inventors, or anyone else at ACS regarding the initial Lau application. (*Id.* at 245:11-248:24). Mr. Lynch did recall, however, that he did not disclose any prior art (presumably including the Boneau prior art) to the PTO because he transferred the file to Mr. Nagy's firm before the IDS was due to be filed. (*Id.* at 248:25-250:1). Mr. Lynch conceded that his duty to disclose material prior art was a continuing one that did not end just because he transferred the file. (D.I. 671, Tr. at 558:8-559:10). Nevertheless, Mr. Lynch could not explain why he never disclosed the Boneau prior art to the PTO. ACS cited Mr. Lynch's "custom and

practice" as proof he acted in good faith. At the same time, however, it denied Medtronic access to Mr. Lynch's January 1990 report, which would have showed his actual state of mind. (*Id.* at 543:17-544:6).

50. Mr. Nagy prosecuted the Lau applications from October 1992 onward. (AX-2586 at LJA 0151). ACS did not call Mr. Nagy to explain why he did not disclose the Boneau patent before August 1997 or why he still has not disclosed all of the Boneau prior art, including the use of multiple Boneau stents, aligned crown-to-crown, or the connection of multiple Boneau stents together with sutures.

51. Along with Mr. Lynch and Mr. Nagy, there were a number of people at ACS who were substantively involved in the prosecution of the various applications that issued as the Lau patents. These included Mr. Lau, Ms. McDermott, Mr. Orth, and Mr. Barclay. Despite their in-depth knowledge of the Boneau prior art, at no time between October 28, 1991 and August 28, 1997, did any of them disclose any of the Boneau prior art to the PTO. (D.I. 671, Tr. at 320:3-13, 321:5-322:21). Moreover, at no time have any of them disclosed the use of multiple Boneau stents in a crown-to-crown configuration or the connection of multiple Boneau stents together with sutures. (*Id.* at 320:14-321:1).

52. Mr. Lau, the lead inventor on the Lau patents, signed an oath acknowledging the duty of candor he owed to the PTO. (D.I. 671, Tr. at 421:12-422:10; AX-2568 at LJA 1437-1455, 1750-1758, 1862-1864, 1977-1979, 2350-2358). Mr. Lau claimed he never saw the Boneau application, and he did not have much information on the Boneau stent in July 1990 when he wrote his Bronco report. (D.I. 671, Tr. at 506:18-507:24, 514:16-515:15, 516:7-23). This claim is not credible.[10] Given the detail of the Bronco report and that there was no publicly available information on the Boneau stent in July 1990, the only way Mr. Lau could have prepared the Bronco report was if he had access to the Boneau application. Mr. Lau also claimed that he had a copy of the Gianturco patent when he wrote his Bronco report and that he believed the Boneau stent was the same as the Gianturco stent. (*Id.* at 468:2-469:22, 506:11-17). That is also not credible. If Mr. Lau thought the Boneau stent was the same as the Gianturco stent, he would

[10] ACS also apparently questions Mr. Lau's credibility: it did not call him as a witness during the liability trial and actually fought to preclude Medtronic from offering any of his deposition testimony.

have simply included the Gianturco stent in his Bronco report, not the Boneau stent.[11] Moreover, Mr. Lau conceded that he never read the Gianturco patent. (*Id.* at 516:7-23). Thus, by his own admission, Mr. Lau had no basis to believe that the two stents were the same.[12] ACS did not elicit any testimony from Mr. Lau on the specific issues of whether he believed the Boneau prior art was material or why the Boneau prior art was not disclosed until August 1997 (and then only partially).

53. Ms. McDermott was ACS's Director of Research and Development. She met with Mr. Lau routinely, talked to Mr. Lynch about the Boneau application, and discussed the Boneau prior art with Mr. Orth. (D.I. 670, Tr. at 239:6-241:12, 262:2-16, 263:22-264:15, 268:20-269:4; D.I. 671, Tr. at 411:24-412:4; DTX-1010). Her responsibilities included seeking patents on ACS's intellectual property and communicating with ACS's outside patent counsel, including Mr. Lynch. (D.I. 670, Tr. at 271:21-272:25; 272:16-25; D.I. 671, Tr. at 552:1-5; 553:17-554:11). However, ACS did not elicit any testimony from Ms. McDermott on whether she believed the Boneau prior art was material or why the Boneau prior art was not disclosed until August 1997 (and then only partially). Instead, Ms. McDermott claimed pure ignorance. Despite the testimony of several witnesses which placed her firmly "at the scene," Ms. McDermott claimed to have no recollection of the name Michael Boneau, of any discussions about the

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[11] Mr. Lau earlier claimed he did not include the Gianturco stent in the Bronco report because it was not "technically relevant to what we were assessing," (D.I. 671, Tr. at 469:13-22), which is hard to imagine given that he allegedly thought it was "the same" as the Gianturco stent, which he did include. Mr. Lau also said he included the Boneau stent because ACS's "management" probably wanted it in the analysis. (*Id.*) This does nothing more than highlight that ACS's management had some interest or concern about the Boneau stent, an interest or concern that ACS concealed from Mr. Boneau.

[12] Even assuming Mr. Lau's testimony were credible, this would not excuse his failure to disclose the Boneau prior art to the PTO. If an applicant is placed on notice of information that potentially may be material, the duty of candor includes a duty of "reasonable inquiry." *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (holding that applicants cannot intentionally avoid learning of prior art). *See also* MPEP §2001.02 (1989) ("[I]f an applicant or an applicant's attorney is aware of facts which indicate a reasonable possibility that a bar to patenting or information material to [the] examination may exist, they are expected to make reasonable inquiries to ascertain such information and to submit such to the [PTO]."). Applicants cannot "cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art." *Brasseler, USA I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1383 (Fed. Cir. 2001). Thus, Mr. Lau had a duty to ascertain whether the Boneau prior art was, in fact, the same as that disclosed in the Gianturco patent. Because ACS did not offer any evidence that Mr. Lau engaged in such an inquiry, and because Mr. Lau conceded that he can't even recall reading the Gianturco patent, the Court can and should conclude that he did not engage in such an inquiry.

Boneau prior art, of any communications with Mr. Lynch regarding the Boneau application, or any steps she took in connection with the Lau patents. (D.I. 670, Tr. at 269:5-20, 273:1-275:1).

54. Mr. Orth was the Business Unit Manager for ACS's Stent Business Unit and the man who commissioned Mr. Lau and Mr. Khosravi to prepare the Bronco report, which included a detailed analysis of the Boneau stent. Mr. Orth met extensively with Mr. Boneau and Dr. Stertzer regarding the Boneau stent, supervised Mr. Lau's and Mr. Khosravi's testing of the Boneau stent, and reviewed the Lau application. (D.I. 670, Tr. at 125:20-127:2; D.I. 671, Tr. at 382:12-25, 402:18-403:1, 416:11-417:2, 419:20-420:6). Mr. Orth had overall responsibility for ACS's Stent Business Unit, which included responsibilities for patenting and for getting information to ACS's outside patent counsel. (D.I. 671, Tr. at 412:8-23) Mr. Orth testified that he believed that the Boneau stent and Mr. Lau's stent were not "related to each other" because the Boneau stent was a single ring stent, whereas Mr. Lau's stent had multiple rings connected to one another. (*Id.* at 394:9-395:1). However, ACS did not elicit any testimony from Mr. Orth on whether he believed the Boneau prior art was material or why the Boneau prior art was not disclosed until August 1997 (and then only partially). Instead, Mr. Orth testified that he did not even recall what he was told about the duty of disclosure or the concept of materiality. (*Id.* at 412:24-413:5).

55. Mr. Barclay was ACS's in-house patent counsel, and later general counsel, and he was the person who sent the Boneau application to Mr. Lynch and received Mr. Lynch's first report on the application. (D.I. 670, Tr. at 208:10-15, 214:5-215:5, 229:9-13, 234:7-237:17, 259:2-9; DTX-1163). Mr. Barclay's responsibilities included receiving disclosures on Mr. Lau's purported inventions, deciding whether to file patent applications on those inventions, monitoring the work of ACS's outside counsel on the prosecution of those applications, and communicating with outside patent counsel. (D.I. 670, Tr. at 211:18-212:19, 214:5-215:1). Despite his responsibilities, ACS did not elicit any testimony from Mr. Barclay about whether he believed the Boneau prior art was material or why the Boneau prior art was not disclosed to the PTO before August 1997 (and why then only partially). Instead, Mr. Barclay claimed that he did not recall ever giving any consideration to disclosing the Boneau prior art and did not recall ever having a view on whether that would have been appropriate. (*Id.* at 215:23-216:13).

ARGUMENT

I. GENERAL INEQUITABLE CONDUCT STANDARDS.

Applicants for patents and their agents and attorneys who are substantively involved in the patenting process have a duty of candor, good faith, and honesty in their dealings with the PTO. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. §1.56. The duty is predicated on the fact that "a patent is the exception to the general rule against monopolies and to the right of access to a free and open market." *Precision Instrument Mfg. Co. v. Automative Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). The duty of candor, good faith, and honesty includes the duty to submit truthful information to the PTO and to disclose to the PTO all information that is known and material to the examination of the application. *Li Second Family Ltd. v. Toshiba Corp.*, 231 F.3d 1373, 1378 (Fed. Cir. 2000). The duty is an "uncompromising" one that must be fulfilled with "the highest degree of candor and good faith." *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949); Manual of Patent Examining Procedure ("MPEP") §2001 (1992) ("The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the [PTO] is aware of and evaluates the teachings of all information material to patentability.").[13]

The duty of candor, good faith, and honesty is a continuing one that exists from the time an application is filed with the PTO until the time the patent issues. *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 803-04 (Fed. Cir. 1990). At the time Lau filed his first application, the MPEP then in effect stated that there is a:

> duty to disclose to the [PTO] all material information they are *aware* of, or reasonably should have been aware of . . . regardless of the source of or how they become aware of the information. Materiality controls whether information must be disclosed to the Office, not the circumstances under which the information is obtained. If material, the information must be disclosed to the Office. The duty to disclose material information extends to information such individuals are aware of prior to or at the time of filing the application or become aware of during the prosecution thereof.

[13] Although the MPEP does not have the force of law, "it is entitled to judicial notice as an official interpretation of statutes or regulations" if it does not conflict with them. *Molins*, 48 F.3d at 1180 n.10.

MPEP §2001.06 (1989). "Once an attorney, or an applicant, has notice that information exists that appears material and questionable, that person cannot ignore that notice in an effort to avoid his or her duty to disclose." *Brasseler*, 267 F.3d at 1383.

A breach of the duty of good faith and honesty by an "affirmative misrepresentation of material fact, failure to disclose material information, or submission of false material information to the PTO, coupled with an intent to deceive," constitutes inequitable conduct. Inequitable conduct with respect to one claim renders all of the claims unenforceable. *Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988). Moreover, "[a] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." *Fox Indus.*, 922 F.2d at 813-04. *See also Consolidated Alum. Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 811-12 (Fed. Cir. 1990) (applicant's inequitable behavior "permeated the prosecution of the other patents-in-suit and renders them unenforceable").

To establish inequitable conduct, the defendant must prove, by clear and convincing evidence, that: (1) the applicant or his agents charged with the duty of candor had knowledge of information; (2) the information was material to the patentability of the claimed invention; and (3) the applicant or his agents misrepresented or failed to disclose that information with the intent to deceive the PTO. *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1318-19 (Fed. Cir. 2000). The inquiries are related. The more evidence that the withheld information was material, the less evidence of intent is required. *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998).

II. THE ACS REPRESENTATIVES HAD KNOWLEDGE OF THE BONEAU PRIOR ART BUT DID NOT TIMELY OR FULLY DISCLOSE IT TO THE PTO.

The evidence is overwhelming that several representatives of ACS who were substantively involved in the patenting process, including at least Mr. Lynch, Mr. Lau, Ms. McDermott, Mr. Orth, and Mr. Barclay, had extensive and contemporaneous knowledge of the Boneau prior art, including: (1) the information set forth in the Boneau application, such as a single-ring, balloon-expandable, plastically deformable, sinusoidal or zigzag-shaped stent, capable of being crimped onto a balloon catheter and

implanted either by itself or in multiples, and in at least some embodiments having a length less than its diameter; (2) the information related to Dr. Stertzer's clinical work implanting multiple Boneau stents aligned in a crown-to-crown or out of phase configuration; and (3) Mr. Boneau's idea of connecting multiple Boneau stents together crown-to-crown using sutures.

However much ACS may try to minimize or explain them away, the following facts paint a vibrant, complete picture of both extensive and contemporaneous knowledge of the Boneau prior art:

(a) In 1989, Mr. Boneau met with Dr. Schneiderman and Mr. Samson, shared prototypes of his stent and discussed technical features of the stent and issues of patentability (*see* Finding 12);

(b) In August 1989, at Dr. Schneiderman's request, Mr. Boneau gave ACS a copy of the Boneau application (*see* Finding 14);

(c) Beginning in 1989, Dr. Stertzer met with Mr. Dollens, Mr. Simpson, Ms. McDermott, and Mr. Orth and shared information with them about the Boneau stent (*see* Finding 11);

(d) In January 1990, Mr. Barclay sent a copy of the Boneau application to Mr. Lynch, who studied the application and sent Mr. Barclay a written report on it (*see* Findings 16-17);

(e) In March 1990, Mr. Lynch obtained a second copy of the Boneau application, studied it again and spoke with Ms. McDermott about it (*see* Findings 22-23);

(f) In July 1990, Mr. Lau and Mr. Khosravi wrote their Bronco report, which contained detailed information about the Boneau stent that could have been derived only from the Boneau application (*see* Findings 24-29);

(g) In August and September 1990, Mr. Boneau and Dr. Stertzer had several meetings with Mr. Lau, Ms. McDermott, Mr. Orth, Mr. Khosravi, and others, and shared information on the physical characteristics of the stent, the clinical work involving the stent, test data, pictures and/or angiographs showing multiple Boneau stents implanted in a single artery in a crown-to-crown configuration, and Mr. Boneau's development of using sutures to connect multiple Boneau stents (*see* Findings 30-33); and

(h) In September 1990, Mr. Lau and Mr. Khosravi tested prototypes of the Boneau stent, and Mr. Orth had discussions with Ms. McDermott about the Boneau prior art. (*See* Finding 34).

ACS cannot credibly deny these facts showing that its representatives who were substantively involved with the prosecution of the Lau patents had actual knowledge of the Boneau prior art before ACS filed for the first Lau application in October 1991. By no later than March 1990, ACS representatives had actual knowledge of, and had been provided with, not one, but two legal opinions on the Boneau application. They knew that the Boneau application was prior art because Mr. Boneau had

provided ACS with the application in August 1989, the same month the application was filed with the PTO. By no later than August or September 1990, ACS representatives had actual knowledge of Dr. Stertzer's clinical work involving the implantation of multiple Boneau stents in a crown-to-crown or "out of phase" configuration. They knew that the clinical work was prior art because Dr. Stertzer and Mr. Boneau had been discussing that work with many of them since the spring of 1989, and Mr. Boneau told them that he and Dr. Stertzer had been working with the Boneau stent since 1988. And by no later than September 1990, ACS representatives had actual knowledge of Mr. Boneau's idea for connecting multiple Boneau stents together using sutures.

Further, ACS cannot hide behind the suggestion that its representatives may not have actually *known* the Boneau prior art predated Mr. Lau's alleged March 2, 1990 conception date or otherwise constituted prior art. As noted above, the ACS representatives clearly knew about all of the Boneau prior art, and they also knew it was prior art because Mr. Boneau and Dr. Stertzer had been telling them about the Boneau prior art since 1989, and Mr. Boneau had emphasized that he and Dr. Stertzer had been working with the Boneau stent since 1988. Moreover, armed with actual knowledge of the Boneau information, if the ACS representatives had any doubts as to whether that information was prior art, they had a duty to conduct a reasonable investigation. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987). They could not sit idly by and engage in a studied ignorance. *Brasseler*, 267 F.3d at 1383. If that is what they did, they are still charged with actual knowledge of the prior art. *Id.*

ACS has never fully disclosed the Boneau prior art to the PTO. The Boneau prior art includes not just the Boneau application, but also the clinical data showing implantation of Boneau rings in a crown-to-crown or out of phase configuration, and the connection of such rings together at their crowns. Instead of disclosing the Boneau prior art when it filed its original Lau application in October 1991, ACS kept completely silent for six years, until August, 1997 when it made a partial disclosure of the Boneau prior art. There was absolutely no disclosure of any of the Boneau prior art during the prosecution of the '154 patent which issued before August, 1997. Although ACS disclosed the Boneau patent during the prosecution of the '167, '168 and '133 Patents, ACS failed to disclose either the implantation of multiple Boneau stents in an out of phase configuration or the connecting of Boneau rings together. ACS did not

offer any explanation why it did not disclose anything for six years, why it made the partial disclosure in August 1997, and why it failed, and continues to fail, to make a full disclosure of the Boneau prior art to the PTO.

III. THE BONEAU PRIOR ART WAS MATERIAL, AND ACS'S REPRESENTATIVES KNEW, OR SHOULD HAVE KNOWN, IT WAS MATERIAL.

Courts have traditionally looked to 37 C.F.R. §1.56 to define materiality. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1393-94 (Fed. Cir. 2003). Prior to 1992, Section 1.56 provided that "[i]nformation is material when there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. §1.56(a) (1986). In 1992, Section 1.56 was amended to provide that prior art is material when it is: (a) not cumulative, and (b) establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim. 37 C.F.R. §1.56(b) (1992). The amended 1992 standard further provides: "[a] prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden of proof standard, giving each term in the claim its broadest reasonable conclusion consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability." *Id*.

Under either standard, any doubt relating to materiality was to be resolved in favor of disclosure. MPEP §2004(10) (1989) ("When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn't consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided."); MPEP §2001.04 (1992) ("It is the patent examiner who should make the determination after considering all of the facts involved in the particular case."); *LaBounty Mfg., Inc. v. ITC*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) ("Close cases should be resolved by disclosure, not unilaterally by the applicant."). Moreover, under either standard, prior art was deemed material even if it would not have actually led to a rejection of any claims in the application. *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1213 (Fed. Cir. 1987); *Atofina v. Great Lakes Chem. Corp.*, 2005 U.S. Dist. LEXIS 7365 (D. Del. Mar. 16, 2005).

The Federal Circuit has applied the pre-1992 standard of materiality to all cases in which the subject patents were prosecuted before 1992. *Dayco*, 329 F.3d at 1364. The Federal Circuit has expressly left undecided the issue of whether to apply the pre-1992 or the 1992 amended standard to cases in which the subject patents were prosecuted after 1992. *Id*. Here, the initial Lau application was filed in October 1991. Thus, the pre-1992 standard certainly should be applied to the prosecution of that application. The Lau patents in suit all issued from continuations of the initial application and claimed the priority date of that application. Thus, the pre-1992 standard should be applied to the prosecution of all of the Lau patents. Nonetheless, Medtronic shows below that the Boneau prior art, individually and certainly collectively, was material to the prosecution of those patents under both the pre-1992 and the 1992 amended standard.

A. The Boneau Prior Art Was Material To The '154 patent Under Both The Pre-1992 And Post-1992 Materiality Standard.

All of the claims of the '154 patent include the "cylindrical element" limitation, which the Court construed as a radially expandable segment of a stent having the L<D relationship. (D.I. 628 at 24). There can be no legitimate question but that the Boneau application discloses a radially expandable stent having the L<D relationship. Indeed, as Medtronic's expert, Dr. Saigal, confirmed, the Boneau application had the most complete disclosure of a stent structure with L<D of all of the prior art that was before the PTO. (D.I. 671, Tr. at 338:11-340:7). Of the over one hundred references ACS disclosed during the prosecution of the '154 patent, only one other prior art reference – the Spiral Palmaz '417 patent – disclosed L<D. (D.I. 671, Tr. at 338:1-10). As Dr. Saigal explained, however, the Spiral Palmaz '417 patent discloses L<D in only one stent state, an expanded state. (*Id.* at 338:11-22; 339:4-7). The Boneau application, on the other hand, discloses L<D in all three stent states: crimped, as manufactured, and expanded. (*Id.* at 328:22-333:23). None of the references cited by ACS disclosed L<D in all three states. (D.I. 671, Tr. at 337:18-21).[14] Moreover, the Boneau application ***expressly*** disclosed L<D in all

[14] Medtronic pointed out in its JMOL motion that ACS's infringement proofs on the L<D relationship of the cylindrical element should have been based on the crimped state. Other Lau claims, however, also claim L<D in the as manufactured and expanded states. Therefore, Lau should have disclosed any art disclosing L<D in any state.

three stent states, whereas the Spiral Palmaz '417 patent only implicitly disclosed L<D in an expanded state (*i.e.*, it could be gleaned only by taking measurements of the figures in the patent). (*Id.* at 338:11-22, 339:18-22).

All of the claims of the Lau '154 patent have connected rings. During the 1990 meetings with numerous ACS representatives, including Mr. Lau, Mr. Boneau disclosed the idea of connecting his stents with sutures. (Finding 50-51). Thus, the Boneau prior art disclosed to ACS included the idea of connecting short, sinusoidal rings, not something disclosed in any other prior art reference.

Focusing on the pre-1992 standard, a reasonable examiner certainly would have considered it important to know about the Boneau application's express and broad disclosure of a ring having L<D in all stent states in deciding whether to allow the '154 patent claims to issue. Thus, the Boneau application, by itself, was material. Moreover, a reasonable examiner also would have considered it important to know about connecting multiple Boneau stents together. And, certainly, a reasonable examiner would have wanted to know that the Boneau prior art included a stent having both the L<D requirement and connections. Thus, under the pre-1992 standard, the Boneau prior art was material. *See* 37 C.F.R. §1.56(a)(1986).

The Boneau application was similarly material under the 1992 amended standard of materiality. The amended 1992 standard requires only a low threshold to show unpatentability. Dr. Saigal testified, in February 2005 and again in June 2005, that Boneau in combination with other prior art references would provide a prima facie case to find claims of the Lau '154 patent unpatentable. (D.I. 636, Tr. at 1367-77; D.I. 671, Tr. at 340:8-22). For example, Dr. Saigal explained that each of the elements found in claim 1 of the '154 patent could be found by taking small stent segments, such as those disclosed in the Boneau patent, and connecting them with the connectors disclosed in the Spiral Palmaz patent. (D.I. 636, Tr. at 1367:1-1369:19). In addition, Dr. Saigal explained in detail how the disclosures of Palmaz and others reflected a general motivation in that art at the relevant time to make stent segments smaller and connect them to avoid instability. (*Id.*).

The Federal Circuit has held that an undisclosed prior art reference is material or even "highly material" when it discloses a number of relevant features or suggests a combination of some of the

elements of the claimed invention. *Semiconductor Energy Lab. v. Samsung Elecs.*, 204 F.3d 1368, 1374 (Fed. Cir. 2000); *Baxter Int'l*, 149 F.3d at 1328. The Federal Circuit also has found that an undisclosed prior art reference is "highly material" when it "discloses a more complete combination of relevant features, even if those features are before the patent examiner in other references." *Semiconductor Energy*, 204 F.3d at 1374. The Boneau application, by itself, disclosed a number of the relevant features claimed in the Lau patents. Moreover, the Boneau application combined with the clinical data that Dr. Stertzer provided, as well as Mr. Boneau's idea of connecting multiple Boneau stents, discloses more of the features claimed in the Lau patents than any other single piece of prior art that was disclosed to the PTO. Exhibit C illustrates this point, showing the obvious step through which the Lau invention (as claimed in cancelled claim 23 of the '790 application, which issued as the '154 patent) can be obtained by combining the stent of the Boneau application plus the connectors of either Spiral Palmaz or the Schatz '984 patent. (*See* Exh. C, hereto).

Finally, Dr. Saigal's testimony about why Boneau's disclosure of L<D is more complete than any other prior art reference that ACS cited shows that Boneau was not cumulative of the other, cited prior art. Accordingly, under either materiality standard, the Boneau prior art was material to the Lau '154 patent and should have been fully disclosed to the PTO.

B. The Boneau Prior Art Was Material To The Lau '167, '168 And '133 Patents Under Both The Pre-1992 And Post-1992 Materiality Standard

ACS's subsequent disclosure of the Boneau '331 patent does not purge its inequitable conduct. First, ACS has no explanation for why it took six years to disclose the Boneau patent, or why it finally decided to disclose that patent after so many years and after three of the Lau patents had already issued. Second, ACS continued to withhold additional material information about the Boneau stent from the PTO – namely, information disclosed to ACS during the various meetings it had with Mr. Boneau and Dr. Stertzer, including the concepts of implanting multiple Boneau stents in a crown-to-crown or "out of phase" configuration, as well as connecting multiple Boneau stents in that configuration.

Specifically, each of the '167, '168, and '133 Lau Patents has claims requiring that the cylindrical elements be aligned in an "out-of-phase" or crown-to-crown configuration. (*See* Lau '167 patent, all

claims; ’168 patent, claims 5-8 and 12-18; ’133 patent, claim 11). All of the claims of these patents also require connections. During the various meetings in 1990 with ACS representatives, Mr. Boneau and Dr. Stertzer disclosed a considerable amount of information about the Boneau stent, including clinical data and pictures showing multiple Boneau stents aligned in a crown-to-crown or “out of phase” configuration. During these meetings, Mr. Boneau told ACS about the idea of connecting multiple Boneau stents using sutures in a crown-to-crown configuration.

Dr. Saigal has opined that the Boneau prior art, in combination with other prior art references, would provide a basis to invalidate at least one claim in each of the Lau ’167, ’168, and ’133 patents containing the “out of phase” limitation. (D.I. 671, Tr. at 335:14-337:13, 340:8-341:23). For example, all of the claims of the ’167 patent have the “out of phase” limitation. (AX-5). Dr. Saigal has testified that the Boneau prior art, in combination with other prior art references, provides a basis to invalidate at least some of these claims. (D.I. 636, Tr. at 1373:11-1375:4). Claim 5 of the ’168 patent contains the “out of phase” limitation. (AX-6). Dr. Saigal testified that the Boneau prior art, in combination with other prior art references, provides a basis to invalidate claim 5 of the Lau ’168 patent. (D.I. 671, Tr. at 341:24–342:15). Finally, Claim 11 of the ’133 patent contains the “out of phase” limitation. (AX-7). Dr. Saigal testified in this case that the Boneau prior art, in combination with other prior art references, provides a basis to invalidate claim 11 of the Lau ’133 patent. (D.I. 671, Tr. at 342:16–343:7). Thus, Dr. Saigal testified that the Boneau prior art, in combination with other references, provides a basis to find Lau patent claims containing the “out of phase” limitation unpatentable. (*See* D.I. 671, Tr. at 335:14-337:13, 341:24-343:7). And, as with L<D, Dr. Saigal testified that the Boneau prior art had a more complete disclosure with respect to the out of phase limitation than other references disclosed by ACS. (D.I. 671, Tr. at 337:22-338:10, 338:23-339:7, 339:23-340:7).

C. ACS Has Not Shown, And Cannot Show, That The Boneau Prior Art Would Have Been Cumulative Or Non-Material.

At trial, ACS asserted that the Lee ’917 patent was cumulative of Boneau. ACS misses the mark for several reasons. As an initial matter, the Lee patent is not even prior art. The Lee patent was filed on April 27, 1990. (DX 1000-79). Mr. Lau claimed to have conceived his invention on March 2, 1990.

Thus, Mr. Lau could have effectively "sworn behind" the Lee patent to avoid any rejection based on that reference. 37 C.F.R. §1.131(a). Section 1.131(a) provides: "When any claim of an application . . . is rejected, the inventor of the subject matter of the rejected claim . . . may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based." *Id.* Thus, the Lee patent is not even prior art to the Lau invention, much less cumulative prior art. For this reason alone, it cannot be considered cumulative of the Boneau prior art for inequitable conduct purposes. Indeed, as ACS's counsel aptly noted during opening statement: "Well, if it's not prior, it's not prior art." (D.I. 670, Tr. at 22:9).

Even if this were not the case, the Lee patent is far less material to Lau than Boneau is, and Lee certainly is not cumulative of the Boneau prior art. Dr. Saigal testified at trial that the Boneau prior art has a more complete combination of features in the context of the Lau patent claims because the Boneau prior art discloses both out of phase and L<D in all stent states; Lee does not disclose either of these characteristics. (D.I. 671, Tr. at 347:20-348:3, 345:10-347:13). Moreover, Dr. Saigal explained that the Lee patent is simply different from the Boneau prior art. (*Id.* at 372:19-373:22). Specifically, the portions of the Lee patent that ACS pointed to (and tried to call rings) are actually just scaffold support members. These support members do not disclose characteristics relevant to Lau such as "L<D" and "out of phase." (*Id.* at 374:15-375:6). Further, the Lee patent discloses "rings" that are spaced apart by 3 to 4 millimeters. (DX 1000-79; D.I. 671, Tr. at 594:9-545:5). Even ACS's expert, Dr. Segal, admitted he would not use a stent to cover a single lesion that had rings spaced that far apart. (*Id.* at 592:15-595:5). The "rings" in the Lee patent have no application to the relevant features disclosed in the Boneau prior art and claimed in the Lau patent claims (*e.g.*, L<D and out of phase).

ACS's assertion that the Boneau prior art is cumulative with the Spiral Palmaz patent is also unconvincing. The Spiral Palmaz patent discloses, at best, L<D and out of phase only in an expanded state. Spiral Palmaz does not disclose, as the Boneau prior art does, L<D and out of phase in all three stent states, including the as manufactured state, the crimped state, and all expanded states. This would have been grounds on which an examiner would have found the Boneau prior art more comprehensive than, and not cumulative with, Spiral Palmaz.

The Boneau prior art collectively disclosed a stent with the L<D relationship in all stent states, the notion of aligning stents in a crown-to-crown or "out of phase" configuration, and the idea of connecting multiple, non-overlapping Boneau stents crown-to-crown.[15] No prior art reference ACS cited during the prosecution of the initial Lau application had a more complete disclosure of each of these features than Boneau did, and no reference ACS cited disclosed the complete combination of all of these features in a stent.

D. ACS's Words And Conduct Confirm The Materiality Of The Boneau Information.

The words and conduct of various ACS representative amply confirm the materiality of the Boneau information they had and chose to withhold. First, Mr. Nagy, on ACS's behalf, expressly admitted not once, but twice – in filings with the PTO in August 1997 – that the Boneau patent, which issued from the Boneau application, was "relevant" to the Lau applications. Indeed, Mr. Nagy filed a separate IDS for the purpose of bringing the Boneau patent to the examiner's attention. In making those admissions, and in actually disclosing the Boneau patent to the PTO, Mr. Nagy acknowledged that there was a substantial likelihood that a reasonable examiner would have considered the Boneau patent important in determining whether to allow the Lau application to issue. The Boneau patent included the same disclosure as the Boneau application that Mr. Boneau provided to ACS, which at least Mr. Lau and Ms. McDermott had access to, and that Mr. Lynch reviewed and reported to ACS about, not once, but

[15] In the liability trial, ACS argued that a Boneau stent having a length less than its diameter, or a length less than four millimeters, would not be functional, citing an article written by Dr. Stertzer. (D.I. 636, Tr. at 1423:8-1424:11; D.I. 637, Tr. at 1574:25-1575:17; DTX 62). ACS's argument is irrelevant to Medtronic's inequitable conduct claim, which focuses solely on the ***disclosures*** in the prior art. The Boneau patent expressly discloses a stent having a length less than its diameter, as short as one millimeter. If ACS thought a Boneau stent having a length less than four millimeters would not be functional, it could have and should have disclosed the Boneau prior art to the PTO and argued its position to the Examiner. Of course, ACS failed to offer any evidence that those involved in the prosecution of the Lau patents ever believed that stents less than four millimeters would not be functional. Moreover, Dr. Stertzer explained that ACS had misconstrued his article and that he never intended to opine on whether a Boneau stent having a length of less than four millimeters would be functional. (D.I. 670, Tr. at 51:6-60:19; 101:23-102:1; AX-62; DTX-1577). In addition, Medtronic's experts, Dr. Robert Wagoner and Dr. Sunil Saigal, testified that there would be no reason why a Boneau stent having a length less than its diameter, or having a length less than four millimeters, ***would not*** be functional. (D.I. 670 at 168:21-173:12; D.I. 671, Tr. at 335:2-13).

twice. Thus, Mr. Nagy's admission that the Boneau patent was material is an equal admission that the Boneau application was also material.[16]

Moreover, ACS's representatives admitted through their conduct that not only was the Boneau application material to the Lau applications, but also that they knew that the Boneau application was material. On Friday, March 2, 1990, Mr. Lau claims to have conceived his stent idea. At that time, Mr. Lau worked for Ms. McDermott and reported directly to her on a regular basis. Thus, Ms. McDermott undoubtedly knew about Mr. Lau's work and his March 2, 1990 conception. By Friday, March 9, 1990, just one week later, Mr. Lynch had contacted Mr. Boneau's patent attorney and asked for another copy of the Boneau application. On Monday, March 12, 1990, Mr. Lynch received the second copy of the Boneau application, reviewed it, and reported to Ms. McDermott about it. Thus, Ms. McDermott not only knew about the Boneau application but also expressed an appreciation for how material the application was to Mr. Lau's design. Ms. McDermott's concern about the Boneau application was so significant that, within days of learning about Mr. Lau's invention, she commissioned and received a report about the Boneau application. This conduct speaks volumes about the materiality of the Boneau application.

IV. THE EVIDENCE CLEARLY AND CONVINCINGLY ESTABLISHES ACS'S INTENT TO DECEIVE THE PTO.

An intent to deceive "need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequence of which are presumably intended by the actor." *Semiconductor*, 204 F.3d at 1374-75. Indeed, direct proof of wrongful intent, or a "smoking gun," is rarely available, and thus intent may and can be inferred from evidence of the surrounding circumstances. *Baxter*, 149 F.3d at 1329; *LaBounty*, 958 F.2d at 1076. Thus, proof of the actual state of mind of the patent applicant and the persons representing the applicant is not required. *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983).

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[16] At trial, ACS argued that Mr. Nagy's admission that the Boneau patent was "relevant" was not an admission that the Boneau patent was "material." This position does not square with the special pains Mr. Nagy took to identify the Boneau patent in an interview with the Examiner and then specially submit it, years after it issued, in an information disclosure with only one other piece of art.

An inference of intent is warranted when a person in the applicant's position knew or should have known that an undisclosed prior art reference would be material to the PTO's consideration. *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1564 (Fed. Cir. 1984). Indeed, the Federal Circuit has held that proof that an applicant failed to disclose a material prior art reference, combined with proof that the applicant knew or should have known of its materiality, "makes it difficult to . . . overcome an inference of intent to mislead." *Semiconductor Energy*, 204 F.3d at 1375; *FMC Corp.*, 835 F.2d at 1415 n.7 ("overwhelming showing of materiality plus an applicant's knowledge of that materiality may raise an inference of intent so strong as to require a convincing showing of subjective good faith to offset it."); *D.O.C.C., Inc. v. Spintech, Inc.*, 36 U.S.P.Q.2d 1145, 1153 (S.D.N.Y. 1994) (intent to deceive can be inferred from an applicant's inexplicable failure to disclose a known and material prior art reference).

A. ACS's Conduct Shows That, With Respect To The Boneau Prior Art, From The Very Beginning, ACS Was Engaged In Deception.

ACS's conduct clearly shows that it intended to deceive the PTO by withholding the Boneau prior art. In 1989 and 1990, ACS spent a substantial amount of time and energy gathering information about the Boneau prior art and exhaustively analyzing it. There is no evidence that any other prior art reference received this kind of attention from Mr. Lynch, or Mr. Lau, or Ms. McDermott, or Mr. Barclay or anyone else at ACS. Yet this was the prior art withheld for six years and then only partly disclosed.

If ACS hoped to convey to the PTO the impression that the Boneau prior art was unimportant, its secret actions betrayed its true views. The speed with which Ms. McDermott contacted Mr. Lynch and the speed with which Mr. Lynch asked for a second copy of the Boneau application, reviewed it for a second time, and then discussed it with Ms. McDermott, all show that ACS appreciated the Boneau prior art was anything but "unimportant." Ms. McDermott obviously knew that ACS was in trouble because the Lau invention so closely resembled what was in the Boneau application. ACS asked Mr. Lynch to review the Boneau application and prepare a report on it, but has steadfastly refused to allow any inquiry into the details of this fifteen-year-old report, notwithstanding the fact that the report is the only contemporaneous record of Mr. Lynch's state of mind (as well as the state of mind of anyone at ACS who received a copy of the report).

Indeed, all of ACS's conduct with respect to the Boneau prior art fits into a pattern of deception. In July 1990, ACS knew enough to prepare the Bronco report covering the ten most promising stent concepts, including the Boneau stent, yet ACS's witnesses, when asked during trial where they got their information about the Boneau stent in the report, conveniently did not recall. The lengths to which ACS would go to cover its tracks with respect to the Boneau prior art are further illustrated by the way in which ACS acquired its knowledge of Boneau's application and work. ACS duped Mr. Boneau and Dr. Stertzer into disclosing everything they knew about the Boneau prior art. Not once, but twice ACS told Mr. Boneau it was interested in his stent, induced him to share information about his work, and then falsely informed him they were not interested in pursuing a stent design program.

ACS played games with both Mr. Boneau and Dr. Stertzer by feigning interest in the Boneau stent. Neither Mr. Boneau nor Dr. Stertzer would have shared all of the information about the Boneau stent with ACS if they knew ACS had already studied the Boneau stent and picked a stent concept. With that history of deception, it is no wonder ACS felt compelled to further deceive the PTO with respect to the Boneau prior art.

B. ACS's Intent To Deceive Is Clear From The Prior Art That It Did Disclose To The PTO.

During prosecution of the initial Lau patent application, ACS disclosed a considerable amount of prior art – over 100 references total, some in the patent specification, the majority in several disclosure statements. (*See* D.I. 671, Tr. at 343:15-345:5). One of the references ACS disclosed was the Haerr '719 patent. (DTX 1000-7). This patent discloses an ear wick; it does not even disclose a stent. Yet, ACS disclosed it. ACS's decision to disclose Haerr shows that ACS must have been applying a broad understanding of materiality in deciding what prior art to disclose to the PTO. Still, ACS did not disclose the Boneau prior art. ACS's intent to deceive the PTO is clear from its choice to bury the PTO in certain prior art, like the Haerr patent covering an ear wick, but not to disclose the Boneau prior art, which covers a stent concept closely related to the Lau invention.

From 1991 to 1997, ACS filed at least six Lau patent applications and never disclosed a thing about the Boneau prior art to the PTO. ACS has not offered any explanation for this failure to disclose.

C. ACS's Partial Disclosure Of The Boneau Prior Art In August 1997 Shows Intent To Deceive.

The inference of intent is compounded and cemented by the fact that, when ACS ultimately did disclose the Boneau patent to the PTO – twice in August 1997 – it did so at a time and in a manner plainly calculated to minimize the scrutiny the art would receive. And it did so, apparently, only in contemplation of filing suit against AVE (which it did later in 1997), with its back to the wall, and probably thinking it could "purge" its early inequitable conduct by getting a patent issued over the Boneau patent. And that is what ACS did. ACS disclosed the Boneau patent, got its notice of allowance within weeks, quickly paid its issuance fee, and then marched into court to sue AVE.

D. ACS's Failure To Offer Any Evidence Of Good Faith Establishes ACS's Intent To Mislead The PTO.

Upon a prima facie showing of inequitable conduct, the burden of proof shifts to the patentholder to come forward with evidence that negates a finding of inequitable conduct. *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993). A patentholder's mere averments of good faith or a lack of deceptive intent is not sufficient to carry the burden. *Id.* at 1190. Similarly, a patentholder's "conclusory statements or completely unsupportable, specious, or conflicting explanations or excuses [also] will not suffice . . ." to meet the burden. *Id.* Medtronic showed above that the Boneau prior art was highly material to the Lau patent claims. Indeed, ACS's patent counsel admitted that the Boneau patent was material to the Lau patents – twice – in August 1997. Medtronic also showed above that there are more than enough facts from which to infer ACS's intent to deceive. Indeed, given the high-level of knowledge and materiality of the Boneau prior art, an intent to deceive is inescapable. Thus, the burden of proof shifted to ACS to come forward with evidence that negates a finding of inequitable conduct. *See Paragon Podiatry*, 984 F.2d at 1191. Indeed, the Federal Circuit has recognized that, when faced with a high level of materiality, as ACS is here, it needs to make a "convincing" showing of subjective good faith to overcome the high degree of materiality. *See FMC*, 835 F.2d at 1415 n.7.

ACS did not submit any such evidence, much less make a convincing showing of its good faith. Instead, ACS made the conscious decision to assert the attorney-client privilege as to all communications regarding the Lau prosecution. This leaves ACS without any evidence of good faith about its decision to

withhold the Boneau prior art from the PTO. That should end the inquiry and compel a finding of inequitable conduct.

E. ACS Cannot Overcome Its Failure To Offer Evidence Of Good Faith.

ACS may try to overcome its failure to introduce evidence of subjective good faith by claiming that it did, in fact, introduce such evidence. Nothing ACS can point to in the record, however, will help it overcome its failure of proof, and, indeed, ACS's arguments are irrelevant and inadmissible.

ACS may point to testimony from its expert, Dr. Segal, that, in his opinion, Boneau is not material to Lau. This litigation-induced testimony, which comes years after the fact, is legally irrelevant. First of all, ACS did not make any showing that any of the people involved with the prosecution of the Lau patents had this in mind when deciding not to disclose any of the Boneau prior art. Moreover, under the 1992 amended standard of materiality, materiality is determined without any consideration to evidence that may be submitted in an attempt to establish patentability." 37 C.F.R. §1.56(b).

ACS is likely to argue that Mr. Lau and Mr. Orth both thought that the Lau stent and the Boneau stent were different. Even if this were true, it is completely irrelevant. The inequitable conduct legal standard has nothing to do with whether prior art was "different." Prior art is almost always different, in at least some way. The question is whether the art was material, and here, the Boneau prior art was highly material to the Lau patent claims. ACS made no showing that Mr. Lau, Mr. Orth, or anyone else thought otherwise at the times in question. Indeed, ACS cannot make any such showing given that it blocked inquiry into their state of mind through the assertion of the attorney-client privilege.

ACS may argue that Mr. Lynch was aware of his duty of disclosure and generally complied with it. Any evidence of Mr. Lynch's *general* practices has no bearing on the *specific* events at issue in this case and should be excluded as irrelevant. Fed. R. Evid. 401-02. Moreover, any attempt by ACS to extrapolate Mr. Lynch's good faith, in this specific instance, from his general practice would constitute improper character and habit evidence. Fed. R. Evid. 404 and 406. Further, ACS blocked Medtronic's efforts to explore the only specific evidence that exists – Mr. Lynch's January 1990 report on the Boneau application.

Similarly, ACS's attempts to characterize its representatives as "good people" should be rejected

as both irrelevant and as improper character evidence. Discussing ACS's representatives during closing argument, ACS's counsel stated: "These are good, decent people." (D.I. 671, Tr. at 627:2). ACS is simply trying to cover up its failure to come forward with *evidence* of good faith with attorney argument about their good character. Attorney argument is not evidence, and, even if this were not the case, any such evidence is inadmissible. Fed. R. Evid. 404. Moreover, it was ACS that made the deliberate decision not to permit inquiry into state of mind by relying on the attorney-client privilege.

If the Court is inclined to consider this type of character evidence, then Medtronic should have the right to impeach with evidence about specific incidents of bad character. Medtronic believes such evidence exists here. For example, Medtronic believes the report Mr. Lynch wrote about the Boneau application would have shown ACS's intent to deceive the PTO. After all, if that report was beneficial to ACS, it would have produced it and relied upon it. Instead, ACS blocked all of this evidence from coming into the record by asserting the attorney-client privilege. ACS has precluded Medtronic from showing the full extent of the evidence of ACS's bad-faith by hiding behind the assertion of the attorney-client privilege. ACS should not be permitted to use this withheld evidence as both a sword and a shield.

In its closing argument, ACS's counsel argued as follows: "But I hope I have not done my client a disservice by protecting their interests because, as you've seen and heard from these people, ACS is an honorable and good company and they were trying to do the right thing." (D.I. 671, Tr. at 627:24-628:3). There is no *evidence* in the record that ACS was trying to do the right thing, given ACS's choice to keep this evidence out of the record, and any attempt to show otherwise now should be rejected as beyond the scope of the record, irrelevant and improper character evidence.

F. ACS's Collective "Corporate Amnesia" Shows Its Intent To Deceive The PTO

At trial, the Court heard from a number of ACS employees and representatives, either live or by deposition, each of whom had either a selective recall or a total lack of recall of the key events in the case. Mr. Barclay testified that he did not recall whether he even gave any consideration to disclosing the Boneau application to the PTO, even though it was established that he was aware of the Boneau application and received Mr. Lynch's report on that application. (D.I. 670, Tr. at 215:23-216:13). Ms.

McDermott testified that she did not recall even hearing the name Michael Boneau or anything about the Boneau stent, even though it was established that she attended meetings with Mr. Boneau and Dr. Stertzer to discuss the Boneau stent, she talked with Mr. Lynch about his review of the Boneau application, and she talked with Mr. Orth about his evaluation of the Boneau prior art. (*Id.* at 269:5-20; 273:1-275:1). Mr. Lau testified that he had no recollection at all of how he came to learn about the Boneau stent that he included in his Bronco report, and he had only "some general recollection" of his various meetings with Mr. Boneau and Dr. Stertzer. (D.I. 671, Tr. at 475:20-476:14; 508:24-510:2; 506:11-507:24). But, despite his lack of a specific recollection of those meetings, Mr. Lau conveniently claimed to have a vivid recollection that Mr. Boneau did not discuss his idea of connecting multiple Boneau stents with sutures and using the Gianturco patent (which he did not read) to depict a picture of a Boneau stent in his Bronco report. (*Id.* at 479:10-12). Mr. Simpson testified that he did not recall ever knowing anything about the Boneau stent, even though it was established that he had various discussions with Mr. Boneau and Dr. Stertzer and was shown a prototype of the Boneau stent. (*Id.* at 308:8-312:4, 314:9-21). Just like Mr. Lau, Mr. Orth also testified that he had "no idea" how he first came to learn about the Boneau stent that was included in the Bronco report, which he directed to be prepared. (*Id.* at 413:16-20). Finally, Mr. Lynch testified that he had no recollection at all of the Boneau application or any of the steps he took in the prosecution of the initial Lau application. (D.I. 670, Tr. at 228:1-10, 230:25-232:5).

To the extent there were documents that may help refresh ACS's witnesses memory, such as Mr. Lynch's report about the Boneau application, ACS hid their contents. Specifically, ACS concealed the contents of these documents, and precluded any testimony about them, by a steadfast assertion of the attorney-client privilege. ACS's assertion of the attorney-client privilege leaves them with no evidence of ACS's subjective good-faith state of mind in choosing not to disclose the Boneau prior art.

The testimony of ACS's forgetful witnesses does not constitute evidence of good faith, and, therefore, it does nothing to overcome the clear and convincing evidence of ACS's inequitable conduct. This type of testimony does, however, reflect adversely on the credibility of ACS and its witnesses. During the liability trial, ACS told the jury that the Lau invention was a "breakthrough" and "a big advance." (D.I. 638, Tr. at 1767:22-1768:1, 1771:13-20). Thus, ACS's widespread "corporate amnesia"

about the Lau "breakthrough" invention during the inequitable conduct phase is astonishing and provides further support that ACS intended to deceive the PTO by failing to disclose the Boneau prior art.

G. ACS's Intent To Deceive Can Be Inferred From Its Failure To Call Key Witnesses

For the witnesses ACS did call, it failed to come forward with any evidence of good faith. This failure of proof is compounded by witnesses that ACS did *not* call at the time of trial. For example, ACS did not call Ms. McDermott, who was directly involved with the review of the Boneau application and the communications with Mr. Lynch it. ACS also did not call Mr. Nagy, the patent attorney who spent years prosecuting the Lau patent applications without disclosing the Boneau prior art to the PTO. Medtronic could not call these witnesses at the time of trial; they were beyond the subpoena power of the Court. Moreover, Ms. McDermott and Mr. Nagy were uniquely in the control of ACS. ACS could have brought them to trial, or at least taken their depositions and presented their depositions at trial, but ACS did not do so. In such a circumstance, it is appropriate to infer that their testimony would be adverse to ACS. *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1400, n.9 (Fed. Cir. 1986) ("When a party knows of witnesses on a material issue and they are within his control to produce, if the party chooses to not call the witnesses, the fact finder may draw the inference that the testimony would have been unfavorable."). In *A.B. Dick*, the Federal Circuit affirmed the district court finding that the patentee's failure to call the inventor and patent attorney during the trial on inequitable conduct, either live or by deposition, could provide "added inferential evidence of the element of intent." *Id.* at 1399-1400.

H. The Evidence Of ACS's Intent To Deceive The PTO Is More Than Clear And Convincing – It Is Overwhelming And Unrefuted.

The Boneau prior art was obviously important to ACS. It was so important that ACS studied it, analyzed it, tested it, took pictures of it, had attorneys review the patent application – twice – and prepare a report about the Boneau application. In the same time frame ACS was working on the Lau stent, ACS was amassing a considerable amount of information about the Boneau stent.

ACS should have told (and was required to tell) the PTO everything it knew about the Boneau prior art. If ACS thought that Boneau was sufficiently distinguishable from the Lau invention, ACS could have talked to the PTO during prosecution of the Lau patents about why it believed Lau was still

patentable. But ACS chose a different path; it chose to withhold everything, roll the dice, and take its chances that this conduct would never see the light of day.

At the end of the day, all that is left is ACS's intentional (and unexplained) choice to bury all of the information it had about the Boneau prior art for six years while it sought Lau patent protection, and then to make only a partial disclosure of it in August 1997. To this day, ACS is still trying to bury this information by hiding behind forgetful witnesses and the attorney-client privilege. ACS's intent to deceive the PTO is clear from its choices.

CONCLUSION

For all the foregoing reasons, Medtronic respectfully requests this Court enter an Order finding that the Lau '154, '167, '168 and '133 patents are unenforceable due to ACS's inequitable conduct before the U.S. Patent & Trademark Office.

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July 28, 2005

CERTIFICATE OF SERVICE

I hereby certify that on July 28, 2005 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following: Frederick L. Cottrell, III (cottrell@rlf.com), Stuart M. Grant (sgrant@gelaw.com), and Karen Jacobs Louden (kjlefiling@mnat.com).

I further certify that on July 28, 2005 I served copies of the foregoing on the following counsel in the manner indicated:

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